

***Remarks***

Claims 14-17, 32, 36, 37, and 40-47 are pending. Claims 38-41 and claim 48 have been canceled without prejudice. Claims 14-17 and 42-47 stand withdrawn. Claim 32 has been amended. Applicant encloses herewith a declaration under Rule 1.132, as further detailed below.

**Rejection under 35 U.S.C. § 101**

Claims 32, 36, 37, 40, 41 and 48 stand rejected based on the contention that the claimed invention lacks utility. In view of the cancellation of claim 48 herewith, the rejection as imposed for this claim is rendered moot. As for the remaining pending, non-withdrawn claims, Applicant responds as follows.

Applicant agrees with the Examiner in that, in order to satisfy the requirements of 35 U.S.C. § 101, an invention must be found to have patentable utility at the time the application was filed, but for at least the following reasons, disagrees that the instant application lacks such utility.

At the outset, Applicant points out that MPEP § 2107.02 specifies that it is imperative that Office personnel use specificity in setting forth a rejection under 35 U.S.C. 101 and support any factual conclusions because, by using specificity, the applicant will be able to identify the assumptions made by the Office in setting forth the rejection and will be able to address those assumptions properly. Moreover, this section of the MPEP also specifies that a *prima facie* showing of a lack of specific or substantial utility **must** establish that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the applicant to be specific and substantial (Applicant's emphasis).

In imposing the instant rejection, Applicant respectfully submits that the Examiner has incorrectly assumed that, because amplification of the MCT-1 gene in chronic lymphocytic leukemia patients was not observed, there is no substantial utility for the presently claimed antibody. Further, Applicant submits that there is no articulated assertion on the record (and it has not been otherwise established by the Examiner) that it is more likely than not that a person of ordinary skill in the art would consider that the presently claimed antibodies lack a substantial

utility, but as noted *supra*, the MPEP specifies that this **must** be established in order to the present rejection.

In view of the foregoing, Applicant submits that the instant claims are allowable and the rejection should be withdrawn due to a lack of a *prima facie* showing in support of the Examiner's contention that the present invention lacks a substantial utility. However, even if it is assumed that a *prima facie* showing of a lack of patentable utility has been made (an assumption Applicant does not make), MPEP § 2107.02 specifies that Applicant can rebut the showing by using an affidavit or declaration under 37 CFR 1.132.

In view of this guidance provided by the MPEP, the Examiner's attention is respectfully directed to the enclosed declaration of Dr. Leo I. Gordon. As can be seen from Dr. Gordon's declaration, he is presently the Abby and John Friend Professor of Cancer Research and Professor of Medicine at the Northwestern University Medical School, and is a permanent member of the Clinical Oncology Study Section in the Center for Scientific Review at the National Cancer Institute, where he was an ad hoc member from 2001-2004. Further, Dr. Gordon has been since 1998 and is presently the co-chair of the Eastern Cooperative Oncology Group (ECOG) lymphoma committee. Further still, Dr. Gordon was Chief of the Division of Hematology/Oncology and Associate Director for Clinical Sciences at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University from 1996-2006. Therefore, Applicant submits that Dr. Gordon was one skilled in the art at the time the present application was filed (and remains one today).

As can be seen from Dr. Gordon's declaration, he knew Dr. Ronald Gartenhaus, the inventor on the instant application, since 1999 when Dr. Gartenhaus was hired as a faculty member at Northwestern University Medical School. Dr. Gordon states that Dr. Gartenhaus was hired as a faculty member at Northwestern University in part because of his work on the MCT-1 protein, work with which Dr. Gordon was familiar from Dr. Gartenhaus' article entitled "*A novel candidate oncogene, MCT-1, is involved in cell cycle progression*" (Prosniak M, et al. Cancer Res. (1998) Vol. 1, pp 4233-7). A copy of this article is enclosed for the Examiner's reference. Dr. Gordon states that it was evident

to him from the reference that antibodies to MCT-1 protein could have been useful for analyzing MCT-1 protein expression and localization in cells that exhibited dys-regulated growth, for determining whether MCT-1 mRNA expression was correlated with protein expression, and for evaluating compounds for affects on the expression of MCT-1 protein. Dr. Gordon indicates that from a review of the instant application, it appears to him that essentially the same data that is presented in Dr. Gartenhaus' article is included in the application. Dr. Gordon expresses in the declaration his opinion that the uses he points out for antibodies to MCT-1 protein that were evident to him from the article would have also been evident to him from the patent application.

Thus, in view of Dr. Gordon's declaration, Applicant submits it is established on the record that it would have been apparent to one skilled in the art at the time the application was filed that an antibody to the MCT-1 protein would be useful at least for evaluating compounds for effects on the expression of MCT-1 protein, for determining MCT-1 protein expression, for determining whether MCT-1 mRNA expression was correlated with MCT-1 protein expression, and for determining MCT-1 protein expression and localization in cells that exhibit dys-regulated growth (which Applicant points out are not necessarily limited to cancer cells). Applicant submits these are substantial utilities and points out that MPEP § 2107.02 specifies that the applicant does not have to provide evidence sufficient to establish that an asserted utility is true beyond a reasonable doubt, nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty. Instead, evidence will be sufficient if it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely true than not true. Applicant submits Dr. Gordon's declaration establishes that a person of ordinary skill in the art would conclude that Applicant's asserted utility is more likely true than not true, and that this is the case for the application at the time it was filed. Thus, it is respectfully submitted that the rejection has been overcome. The Examiner is accordingly requested to reconsider and withdraw the rejection.

### **Rejections under 35 U.S.C. § 112, First Paragraph**

All of the pending, non-withdrawn claims remain rejected based on the contention that they fail to comply with the enablement requirement. This rejection has been maintained on the same grounds used to impose the rejections based on a contention of a lack of utility as discussed above. Therefore, Applicant reiterates the arguments presented above and respectfully submits that since the lack of utility rejection has been overcome, the rejections based on the contention of a lack of enablement have likewise been overcome. The Examiner is therefore respectfully requested to reconsider and remove the stated rejection.

### **New Grounds for Objection and Rejections**

All of the pending, non-withdrawn claims have been objected to based on recitation of the term "MCT-1". Applicant has accordingly amended claim 32 to specify that the antibody binds with specificity to a protein comprising the sequence of SEQ ID NO:8, per the Examiner's suggestion in the Office Action. The Examiner is respectfully requested to withdraw the objection.

All of the pending, non-withdrawn claims have been rejected under 35 U.S.C. 101 based on the contention that they are directed to non-statutory subject matter because they do not distinguish over naturally occurring antibodies. In response, Applicant has herewith amended claim 32 to specify that the claimed antibody is "isolated", per the Examiner's suggestion. The Examiner is respectfully requested to withdraw the rejection.

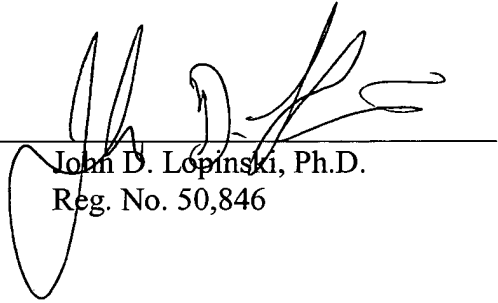
Claims 40-41 have been rejected based on the contention that they fail to comply with the written description requirement. In order to expedite the allowance of the present application, Applicant has herewith canceled claims 40-41 without prejudice. Thus, the rejection of these claims is rendered moot, and the Examiner is requested to remove the stated rejection.

***Conclusion***

Based on the arguments and amendments presented herein, Applicant believes all the pending claims are now in condition for allowance and respectfully requests the Examiner to allow all the claims. Applicant requests a one-month extension of time to file the instant response. The fee and any other fees due during prosecution of this application may be charged to deposit account number 08-2442.

Respectfully submitted,  
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